



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/553,745	10/18/2005	Christopher John Douglas Pomfrett	39-314	6133
23117	7590	04/07/2008	EXAMINER	
NIXON & VANDERHYE, PC 901 NORTH GLEBE ROAD, 11TH FLOOR ARLINGTON, VA 22203				STOUT, MICHAEL C
ART UNIT	PAPER NUMBER	3736		
MAIL DATE	DELIVERY MODE	04/07/2008	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)
	10/553,745	POMFRETT ET AL.
	Examiner	Art Unit
	MICHAEL C. STOUT	3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on ____.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 22-40 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) Claim(s) ____ is/are allowed.
- 6) Claim(s) 22-40 is/are rejected.
- 7) Claim(s) ____ is/are objected to.
- 8) Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on ____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. ____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. ____ .
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>4/24/2006 and 10/18/2005</u>	5) <input type="checkbox"/> Notice of Informal Patent Application
	6) <input type="checkbox"/> Other: ____ .

DETAILED ACTION

This detailed action is in regards to United States Patent Application 10/553,745 filed on 10/18/2005 and is a first action based on the merits of the application.

Specification

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. **Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading.** If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
- (e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
- (f) BACKGROUND OF THE INVENTION.
 - (1) Field of the Invention.
 - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (g) BRIEF SUMMARY OF THE INVENTION.
- (h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (i) DETAILED DESCRIPTION OF THE INVENTION.
- (j) CLAIM OR CLAIMS (commencing on a separate sheet).
- (k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses

a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

The specification is missing headings corresponding to some of the above sections. Appropriate correction is required.

Claim Objections

Claims 22, 24 and 29 is objected to because of the following informalities:

Claim 22 measures the response of the nervous system to a stimulus... wherein the predetermined measurement period is initiated after the application of the stimulus, hence claim 22 requires the application of the stimulus. Appropriate correction is required.

Claims 24 is objected to because of the following informalities: Claim 24 cites the measurement is initiated at **a time delayed** relative to the stimulus, and **the time delay** differs for each stimulus, the inconsistent terminology leads to the claim being unclear since there is not a clear antecedent basis for "the time delay."

Also the claim cites the **stimulus comprise a series of stimuli** but the rest of the claim refers to **each stimulus**, and it is unclear whether there are a plurality of stimulus each having a series of stimuli or one stimulus having a series of stimuli, because previously reference is made to a stimulus.

Appropriate correction is required.

Claims 29 is objected to because of the following informalities: Claim 29 states "said detection starts computation of the said predetermined time," it is unclear from the claim or written description what is being computated, does the detection signal start computation of what the predetermined time should be prior to measurement or does the detections signal start the computation of counting the said predetermined time prior to measurement.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 24 ,25 and 33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 24 recites the limitation "each stimulus" in claim 22. There is insufficient antecedent basis for this limitation in the claim.

Claim 25 recites the limitation "the images" in claim 24. There is insufficient antecedent basis for this limitation in the claim.

Claim 33 recites the limitation "the impedance" in claim 32. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 39 is rejected under 35 U.S.C. 101 because

the claimed invention is directed to non-statutory subject matter.

. Claim 39 cites "a data carrier carrying computer program code means" which includes electromagnetic carrier signals which are used to transmit computer program code.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 22-26, 28-31, 36 and 38-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamazaki et al. (US 5,638,825) in view of John et al. (US 2002/0091335).

Regarding claim 22, Yamazaki teaches a method for monitoring the response of a nervous system of a body to a stimulus (monitors an evoked response of the nervous system, see Abstract), comprising collecting a set of voltage measurements between selected areas on a surface of the body whilst current is passed between selected regions of the surface of the body (the electrodes 21 is used to record a brain potential resulting from a flash and may be attached to each location of the head corresponding to the visual cortex and a reference point the ear lob, see Column 4, Lines 52-67 whilst current is being

passed between regions of the skin electrodes and the ear lobe reference, Column 6, Line 55 through Column 7, Line10), wherein the set of voltage measurements is collected over a predetermined measurement period (the control section 13 receives a signal 202 regarding an evoked potential measure starting time and ending time, see Column 4, Lines 52-67), the predetermined measurement period is initiated a predetermined time after application of the stimulus (a period of time for which the brain potential is to be measured after the flash apparatus is energized to emit light, each time light is emitted from the flash apparatus 23, a signal of the brain potential for the preset time (for example, 3 seconds) after emission of the flash light is recorded onto the evoked potential recording section 14, see Column 6, Lines 45-50 and Column 7, Line 20-25),

Yamazaki fails to teach the system wherein, the collected voltage measurements are compared with reference measurements to determine normal or abnormal response of the nervous system.

John teaches a method for monitoring a nervous system response wherein, the collected measurements are compared with reference measurements (the data is then analyzed and compared to a set of reference values, see [0011]) to determine normal or abnormal response of the nervous system (information can then be used to detect a normal (reference values) or abnormal (deviation from reference values) response to the stimulus to detect a physiological state, see [0017]).

Both Yamazaki and John teach methods for monitoring a nervous system response to a stimulus.

Thus, it would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the method taught by Yamazaki to include comparing measured values to reference values as taught by John in order to generate a report showing the patients statistical "normal" and "abnormal" regions, see John [0041] and [0042].

Regarding claim 23, Yamazaki in view of John further teaches the method according to claim 22, wherein the set of voltage measurements is used to produce an image representing the distribution of impedance within the body (A printer 49 may be used to print out a report on the patient. Preferably the printer is a color printer which is used to generate a topographic "heat scale" color-coded map of the patient's head showing, by its colors, the patient's statistical "normal" and "abnormal" regions., see John [0042]).

Regarding claim 24, Yamazaki in view of John further teaches the method according to claim 22, wherein the stimulus comprises a series of stimuli (Yamazaki teaches applying a series of stimuli, after each lapse of the preset time interval (for example, 5+.alpha. seconds), next emission of light is attempted. the procedure is repeated by a number of times equal to the preset stimulus application time number (for example, 100 times), see Column 7, Lines 25-40), a set of voltage measurements is collected during current injection periods initiated after the application the stimulus (the measurement period for a each stimulus begins after a delay, as stated above: a period of time for which the brain

potential is to be measured after the flash apparatus is energized to emit light, see Column 6, Lines 45-50 and Column 7, Line 20-25), the collection of voltage measurements related to the stimulus is initiated at a time delayed relative to the respective stimulus (the stimulus measurement period begins after the flash, thus there being a time delay between the flash and measurement), the time delay differs for each stimuli (each stimuli has its own measurement period which begins after the flash (a time delay) thus each measurement period has its own different time delay), and differences between collected sets of voltage measurements are interpreted as representing changes in nervous system activity over the time difference between the respective time delays (the measurements are averaged incorporating the differences between measurements which represent changes in the nervous system over time between the delayed pulses, resulting from the stimuli, see Figure 5, Column 8 Line 44 through Column 9, Line 25) .

Regarding claim 25, Yamazaki in view of John further teaches the method according to claim 24, wherein the set of voltage measurements is used to produce an image representing the distribution of impedance within the body (A printer 49 may be used to print out a report on the patient. Preferably the printer is a color printer which is used to generate a topographic "heat scale" color-coded map of the patient's head showing, by its colors, the patient's statistical "normal" and "abnormal" regions, see John [0042]) and the image data are compared to identify changes in nervous system activity (John also teaches

using a patients own previous data in [0011] to generate reference data thereby showing a normal or abnormal change in nervous system activity).

Regarding claim 26, Yamazaki in view of John further teaches the method according to claim 22, wherein the applied stimulus is a visual (flash apparatus 23) or an auditory stimulus.

Regarding claim 28, Yamazaki in view of John further teaches the method according to claim 22, further comprising applying the stimulus (controller sends a signal to energize the flash and the flash response is measured, see Column 7, Lines 16-39).

Regarding claim 29, Yamazaki in view of John further teaches the method according to claim 22, wherein application of the stimulus is detected (the system measurement control section detects a stimulus is generated when the control section 20, sends a signal 202, to the measurement control section 13, after sending a signal 201 to energize the stimulator 11, Yamazaki Column 4, Lines 52-63) and said detection starts computation of the said predetermined time (the control section 13 receives the signal 202 and records after the stimulus form the flash apparatus, see Yamazaki Column 7, Lines 20-30).

Regarding claim 30: Yamazaki in view of John further teaches the method according to claim 29, wherein the stimulus occurs spontaneously (the

experimenter will input data into the control section 20 including a time interval 5+alpha wherein alpha is a random number between 0-1, which has not been predetermined, see Yamazaki Column 6, Line 40-45, thereby generating spontaneous stimulus for the user).

Regarding claim 31: Yamazaki in view of John further teaches the method according to claim 30, wherein the stimulus is a feature of an environment in which the body is located (Yamazaki, Figures 1 and 2 shows a stimulus device which provides a visual flash, the device and flash being a feature of the environment where the patients body is located).

Regarding claim 36, Yamazaki teaches an apparatus for monitoring the response of a nervous system of a body to an applied stimulus (monitors an evoked response of the nervous system, see Abstract) comprising means for applying the stimulus to the body (flash stimulator 23), and means for collecting a set of voltage measurements between selected areas on a surface of the body (the electrodes 21 is used to record a brain potential resulting from a flash and may be attached to each location of the head corresponding to the visual cortex and a reference point the ear lob, see Column 4, Lines 52-67 whilst current is being passed between regions of the skin electrodes and the ear lobe reference, Column 6, Line 55 through Column 7, Line10), wherein the set of voltage measurements is collected over a predetermined measurement period, the predetermined measurement period is initiated at a predetermined time after

application of the stimulus (a period of time for which the brain potential is to be measured after the flash apparatus is energized to emit light, each time light is emitted from the flash apparatus 23, a signal of the brain potential for the preset time (for example, 3 seconds) after emission of the flash light is recorded onto the evoked potential recording section 14, see Column 6, Lines 45-50 and Column 7, Line 20-25).

Yamazaki fails to teach the apparatus comprising a means are provided to compare the collected voltage measurements with reference measurements to determine normal or abnormal response of the nervous system.

John teaches an apparatus for monitoring a nervous system response comprising a means are provided (a computer system 40 comprising a processor 42 and memory 41 which can transmit and store data and a printer 49 to print normal and abnormal responses [0040]-[0042] the data is then analyzed and compared to a set of reference values, see [0011]) to compare the collected voltage measurements with reference measurements to determine normal (reference values) or abnormal (deviation from reference values) response to the stimulus to detect a physiological state, see [0017]).

Both Yamazaki and John teach an apparatus for monitoring a nervous system response to a stimulus.

Thus, it would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the apparatus taught by Yamazaki to include a means for comparing measured values to reference values as taught

by John in order to generate a report showing the patients statistical "normal" and "abnormal" regions, see John [0041] and [0042].

Regarding claim 38, Yamazaki teaches a method for diagnosing a physiological condition, comprising collecting a set of voltage measurements between selected areas on a surface of the body whilst current is passed between selected regions of the surface of the body (the electrodes 21 is used to record a brain potential resulting from a flash and may be attached to each location of the head corresponding to the visual cortex and a reference point the ear lob, see Column 4, Lines 52-67 whilst current is being passed between regions of the skin electrodes and the ear lobe reference, Column 6, Line 55 through Column 7, Line10), wherein the set of voltage measurements is collected over a predetermined measurement period (the control section 13 receives a signal 202 regarding an evoked potential measure starting time and ending time, see Column 4, Lines 52-67), the predetermined measurement period is initiated a predetermined time after application of the stimulus (a period of time for which the brain potential is to be measured after the flash apparatus is energized to emit light, each time light is emitted from the flash apparatus 23, a signal of the brain potential for the preset time (for example, 3 seconds) after emission of the flash light is recorded onto the evoked potential recording section 14, see Column 6, Lines 45-50 and Column 7, Line 20-25),

Yamazaki fails to teach the system wherein, the collected voltage measurements are compared with reference measurements to determine normal or abnormal response of the nervous system.

John teaches an apparatus for monitoring brain dysfunction (see [0017]) wherein, the collected measurements are compared with reference measurements (the data is then analyzed and compared to a set of reference values, see [0011]) to determine normal or abnormal response of the nervous system (information can then be used to detect a normal (reference values) or abnormal (deviation from reference values) response to the stimulus to detect a physiological state, see [0017]).

John teaches a method for monitoring a nervous system response. Both Yamazaki and John teach methods for monitoring a nervous system response to a stimulus.

Thus, it would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the method taught by Yamazaki to include comparing measured values to reference values as taught by John in order to generate a report showing the patients statistical “normal” and “abnormal” regions, see John [0041] and [0042].

Regarding claims 39 and 40, Yamazaki in view of John teaches performing the method of claim 22 as set forth above.

Yamazaki teaches a programmable control apparatus

John teaches a computer apparatus (Figure 1) comprising a memory [data carrier carrying computer program code means to cause a computer to execute a procedure] (internal memory of approximately 100MB, see [0036]) and a processor (microprocessor, [0035]) for reading and executing instructions from said memory, wherein the memory comprises instructions, see [0018]).

Both Yamazaki and John teach monitoring devices.

Thus, it would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the apparatus taught by Yamazaki to include a computing apparatus comprising memory and a processor for executing a method as taught by John, in order to perform the method of claim 22 above taught by Yamazaki in view of John in order to generate a report showing the patients statistical “normal” and “abnormal” regions, see John [0041] and [0042]. One of ordinary skill in the art would recognize that the implementation of a method on a using instructions stored in memory, is a known well known means for implementing a method, if this leads to the anticipated success, it is likely the product is not of innovation but of ordinary skill and common sense.

Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yamazaki et al. (US 5,638,825) in view of John et al. (US 2002/0091335) and in further view of Vauhkonen et al. (“*A Kalman Filter Approach to Track Fast Impedance Changes in Electrical Impedance Tomography*,” IEEE Transactions on Biomedical Engineering, Vol 45, NO. 4, April 1998).

Yamazaki in view of John teaches a method of recording voltages to make an impedance image, see John [0042].

Yamazaki in view of John fails teach a method wherein the measured voltages are filtered using a Kalman filter.

Vauhkonen teaches a method of making an image using voltage measurements wherein the measurements are filtered using a Kalman filter, see Abstract.

Both Yamazaki/John and Vauhkonen teach methods for monitoring a nervous system response to a stimulus.

Thus, it would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the method taught by Yamazaki/John to include filtering measurements using a Kalman filter as taught by Vauhkonen in order track fast impedance changes in the impedance distribution, see Vauhkonen Abstract.

Claim 32, 34 and 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yamazaki et al. (US 5,638,825) in view of Polydorides. et al. ("Krylov Subspace Iterative Techniques: on Detection of Brain Activity with Electrical Impedance Tomography," IEEE Transactions on Medical Imaging, Vol. 21 No. 6, June 2002).

Regarding claim 32, Yamazaki teaches a method for monitoring the response of a nervous system of a body to a stimulus (monitors an evoked

response of the nervous system, see Abstract), comprising identifying the predetermined part of the nervous system (the electrodes 21 is used to record a brain potential resulting from a flash and may be attached to each location of the head corresponding to the visual cortex and a reference point the ear lob, see Column 4, Lines 52-67), applying the stimulus (a flash is applied, see Column 7, Lines 16-39), and collecting a set of voltage measurements between selected areas on the surface of the body (voltage measurements are taken between cortex electrodes and the reference O V ear lobe electrode), wherein the said regions and/or areas are selected on the basis of a neurological model of the nervous system and the applied stimulus (the electrode positions are based on measuring a response to a visual stimulus and are thus placed around the visual cortex of the brain) such that sensitivity of the derived impedance measurements to changes in the predetermined part of the nervous system is maximized (One of ordinary skill in the art would recognize that the placement of the electrodes near the visual cortex region of the brain will provide a better indication of response (maximize the sensitivity) to a visual stimulus than placing the electrodes distally from the region).

Polydorides teaches a method of detecting brain activity particually with response to visually stimulation (I. Introduction Paragraphs 1 and 2) comprising passing current between selected regions of a surface of the body, and collecting a set of voltage measurements between selected areas on the surface of the body whilst current is being passed (see I. Introduction Paragraph 1),

wherein the said regions and/or areas are selected on the basis of a neurological model of the nervous system and the applied stimulus such that sensitivity of the derived impedance measurements to changes in the predetermined part of the nervous system is maximized (Polydorides also teaches the placement of electrode patters are deliberately placed where the targeted effect was “expected” to occur in order to enhance the system’s sensitivity in that particular region, see Page 601, Column 1, Paragraph 2).

Both Yamazaki and Polydorides teach methods for monitoring a nervous system response to a stimulus.

Thus, it would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the method taught by Yamazaki to include injecting currents and collecting voltages as taught by Polydorides in order to generate an image which shows activity in the brain in a region of interest, see I. Introduction Paragraphs 1-3, and Figure 4.

Regarding claim 34, Yamazaki in view of Polydorides further teaches the method according to claim 22, wherein the applied stimulus is a visual (flash apparatus 23) or an auditory stimulus.

Regarding claim 37, Yamazaki teaches an apparatus for monitoring the response of a predetermined part of a nervous system of a body to an applied stimulus (monitors an evoked response of the nervous system, see Abstract),,

comprising means for applying the stimulus (flash stimulator 23), and means for collecting a set of voltage measurements between selected areas on the surface of the body (the electrodes 21 is used to record a brain potential resulting from a flash and may be attached to each location of the head corresponding to the visual cortex and a reference point the ear lob, see Column 4, Lines 52-67), applying the stimulus (a flash is applied, see Column 7, Lines 16-39), wherein the said regions and/or areas are selected on the basis of a neurological model of the nervous system and the applied stimulus (the electrode positions are based on measuring a response to a visual stimulus and are thus placed around the visual cortex of the brain) such that the sensitivity of the derived impedance measurements to changes in the predetermined part of the nervous system is maximized (One of ordinary skill in the art would recognize that the placement of the electrodes near the visual cortex region of the brain will provide a better indication of response (maximize the sensitivity) to a visual stimulus than placing the electrodes distally from the region).

Polydorides teaches a simulated device for detecting brain activity particularly with response to visually stimulation (I. Introduction Paragraphs 1 and 2) means for passing current between selected regions of the surface of the body (electrodes shown in Figure 3), and means for collecting a set of voltage measurements (Electrodes in Figure 3) between selected areas on the surface of the body whilst current is being passed (see I. Introduction Paragraph 1, One of ordinary skill in the art would recognize that the simulated placement of electrodes can be implement using actual electrodes in an apparatus).

Polydorides also teaches the placement of electrode patters are deliberately placed where the targeted effect was “expected” to occur in order to enhance the system’s sensitivity in that particular region, see Page 601, Column 1, Paragraph 2.

Both Yamazaki and Polydorides teach monitoring a nervous system response to a stimulus.

Thus, it would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the apparatus taught by Yamazaki to include a means for injecting currents and means for collecting measurements as taught by Polydorides in order to generate an image which shows activity in the brain in a region of interest, see I. Introduction Paragraphs 1-3, and Figure 4.

Claims 33 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamazaki et al. (US 5,638,825) in view of Polydorides. et al. (“Krylov Subspace Iterative Techniques: on Detection of Brain Activity with Electrical Impedance Tomography,” IEEE Transactions on Medical Imaging, Vol. 21 No. 6, June 2002) and in further view of John et al. (US 2002/0091335).

Yamazaki in view of Polydorides teaches the method of claim 32 above wherein the set of voltage measurements is collected over a predetermined measurement period (the control section 13 receives a signal 202 regarding an evoked potential measure starting time and ending time, see Column 4, Lines 52-67), the predetermined measurement period is initiated a predetermined time after application of the stimulus (a period of time for which the brain potential is to

be measured after the flash apparatus is energized to emit light, see Column 6, Lines 45-50 and Column 7, Line 20-25),

Yamazaki in view of Polydorides fails to teach the method of claim 32 wherein, the voltage measurements are compared with reference measurements to determine normal or abnormal response of the nervous system.

John teaches a method for monitoring a nervous system response wherein, the collected measurements are compared with reference measurements (the data is then analyzed and compared to a set of reference values, see [0011]) to determine normal or abnormal response of the nervous system (information can then be used to detect a normal (reference values) or abnormal (deviation from reference values) response to the stimulus to detect a physiological state, see [0017]).

Both Yamazaki/Polydorides and John teach methods for monitoring a nervous system response to a stimulus.

Thus, it would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the method taught by Yamazaki to include comparing measured values to reference values as taught by John in order to generate a report showing the patients statistical “normal” and “abnormal” regions, see John [0041] and [0042].

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See Form 892 for pertinent prior art not relied upon, along with additional information of the references cited in this office action.

Contact Info

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL C. STOUT whose telephone number is (571)270-5045. The examiner can normally be reached on M-F 7:30-5:00 Alternate (Fridays).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. C. S./
Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736